

Section II (Remarks)

A. Summary of Amendments to the Claims

By the present amendment, claim 31 has been amended to eliminate an antecedent basis problem. Claim 31 depends from claim 29, which recites a first block valve and a second block valve. Prior claim 31 referred to “the block valve” without making proper reference to the first and second block valves. By the present amendment, such deficiency is cured. Such amendment is fully supported by and consistent with the disclosure of the present application. No new matter within the meaning of 35 U.S.C. 132(a) has been introduced by the amendment to claim 31.

B. Response to Claim Rejections Under 35 U.S.C. 102

In the July 8, 2008 Office Action, claims 35-39 and 43 were rejected under 35 U.S.C. 102 as being anticipated by U.S. Patent No. 5,693,017 to Spears et al. (“Spears”). Such rejections are traversed.

1. Law Regarding Anticipation Rejections under 35 U.S.C. § 102

“Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration.” *W.L. Gore & Assocs. v. Garlock*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). It is not enough that the prior art reference disclose all the claimed elements in isolation. Rather, **“anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim.”** *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added). Further, “[u]nder 35 U.S.C. § 102, anticipation requires that ... the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public.” *Akzo, N.V. v. United States Int’l Trade Comm’n*, 808 F.2d 1471, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986).

2. Patentable Distinctions of Claims 35-39 and 43 Over Spears

Claims 35-39 and 43 include one independent claim – namely, claim 35, as reproduced below:

35. A method for dispensing a liquid from a container including an outer container and an inner container, with a portion of the inner container initially

occupied by a liquid, and with a **remainder of the inner container initially occupied by a headspace gas**, the method comprising:

evacuating the headspace gas from the inner container;

following said evacuating step, introducing an amount of empty detect gas into the inner container; and

compressing the inner container to force liquid from the inner container.

Spears discloses a bag 22 (e.g., inner container) disposed within a vessel 20 (e.g., outer container), and the use of the same pressurized oxygen source (i.e. canister shown at left in Spears FIG. 1) to (1) supply oxygen to bag (inner container) 22 to oxygenate blood therein; and (2) pressurize the vessel 22 (or outer container) to apply external pressure to the bag 22 (or inner container) for the dual purposes of (a) promoting dissolution of oxygen bubbles in the blood contained by the bag 22, and (b) compress the bag 22 to expel the oxygen-supersaturated blood at a desired flow rate through a delivery tube 56 (connected to trocar 26).

In comparing U.S. Patent No. 5,693,017 to Spears (“Spears”) to claim 35, the July 9, 2008 Office Action states the following at page 2 thereof:

The device of Spears performs the claimed method steps of introducing an amount of gas into the inner container prior to dispensing, evacuating the head space via a gas valve 36, closing the gas valve to supply a gas under pressure between the inner container and the outer container to force out the liquid from the inner container and sensing the gas by sensor 66 as claimed in method claims 35-39, see column 5, lines 8-24.

Column 5, lines 8-24 of Spears (as referenced in the Office Action to support the foregoing rejection of claim 35) is reproduced below:

After placement of the bag 22 in the vessel 20, a dip trocar or trocar 26 within the bag is used to bubble oxygen at a target partial pressure, on the order of 2–3 bar. The space 24 external to the container is pressurized by the same oxygen source that pressurizes the trocar 26. Allowing oxygen to leak at a slightly faster flow rate from the space outside the bag compared to the bubble flow rate ensures that a differential pressure of a few psi is obtained which permits the flow of oxygen through the trocar 26 at an appropriate rate.

Once the solution in the bag 22 has reached the target partial pressure of oxygen, flow through the dip trocar 26 is stopped and the oxygen pressure external to the bag is increased slightly to drive out any pockets at the top of the bag. The same source of oxygen is then used to increase the oxygen pressure in the vessel 20 to provide hydrostatic pressure for achieving liquid flow rates required for the coronary artery application.

Thus, the foregoing passage of Spears discloses the following steps:

- (1) supplying oxygen to an inner container (i.e., bag 22);
- (2) following the supplying step, slightly increasing oxygen pressure in the outer container (vessel 20) external to the inner container (bag 22) to drive out any pockets of oxygen from the inner container; and
- (3) further increasing oxygen pressure in the outer container (vessel 20) external to the inner container (bag 22) to compress the inner container to dispense oxygenated blood from the inner container through trocar 26 and delivery tube 56.

Nothing in Spears discloses any empty detect gas that is introduced into an inner container following evacuation of a headspace gas from such inner container.

A comparison between claim 35 and the disclosure of Spears is set out below.

Applicants' Claim 35	Closest disclosure of Spears
"Evacuat[e] the headspace gas from inner container"	Drive out pockets of oxygen
"Following said evacuation step, introduce[e] an amount of empty detect gas into the inner container"	NO SUCH STEP IS TAUGHT BY SPEARS; Spears clearly discloses that oxygen is introduced into the bag <u>before</u> (NOT following) any pockets of oxygen are driven out
Compressing the inner container to force liquid from the inner container	Compressing the bag 22 to dispense oxygenated blood

Spears repeatedly refers to the need to eliminate oxygen pockets and bubbles from any blood delivered to the patient. This is consistent with Spears' method, which teaches that oxygen pockets should be driven out of the bag 22 just prior to compression of such bag to dispense blood therefrom. If gas (e.g., oxygen) were further introduced into Spears' inner bag after the evacuation step, then bubbles would be delivered into the patient's bloodstream with potentially lethal consequences.

Because Spears fails to disclose "**following said evacuating step**, introducing an amount of empty detect gas into the inner container," as required by method claim 35, the rejection of such claim (and all claims depending therefrom) should be withdrawn.

B. Applicant's Summary of Telephonic Interview With the Examiner on July 30, 2008

The undersigned attorney spoke telephonically with Examiner Cartagena on July 30, 2008 to discuss the substance of the July 8, 2008 Office Action. The undersigned attorney raised the same arguments identified above to distinguish claim 35 over Spears. In the course of such telephonic interview, **the examiner conceded that he had previously misinterpreted the disclosure of Spears, and that the rejection of claims 35-39 and 43 did not appear to be proper over such disclosure.** The undersigned attorney asked whether it may be possible for the examiner to retract the final office action in view of the clear misapplication of Spears to claims 35-39 and 43. The examiner indicated that he would check with his supervisory patent

examiner to discuss procedural options and identify the best course for the undersigned attorney to expedite allowance of the application.

Despite leaving at least four (4) telephone messages with Examiner Cartagena after the July 30, 2008 telephonic interview, the undersigned attorney has not received any further telephone call or other communication from the examiner.

CONCLUSION

Based on the foregoing, all of Applicants' pending claims are patentably distinguished over the art, and in form and condition for allowance. The examiner is requested to favorably consider the foregoing, and to responsively issue a Notice of Allowance without delay. If any issues require further resolution, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,

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